

**REMARKS**

Claims 1 – 15 and 19 – 21 are currently pending, with Claims 14 and 15 having been withdrawn from consideration. Claims 1 and 20 are the pending independent claims. In the Office Action, the Examiner rejected Claims 16 and 18 under Section 112, second paragraph as allegedly being indefinite and under Section 101. Claim 18 was also rejected under Section 112, first paragraph as allegedly lacking enablement. Claim 2 was rejected under Section 112, first paragraph as allegedly failing to satisfy the written description requirement. Further, Claims 1 – 13, and 18 were rejected under Section 112, second paragraph as allegedly being indefinite.

On the merits, Claims 1 and 3 – 13 were rejected as allegedly being anticipated by US Patent No. 4,992,419 to Woog et al. (“Woog”). In addition, Claim 16 was rejected as allegedly being obvious over the Woog patent taken in combination with US Patent No. 4,647,454 to Cymbalista. Finally, Claims 1 – 13, 16, and 18 were provisionally rejected for alleged obviousness-type double patenting based upon Claims 1 – 20 of copending application 10/521,298.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. **The Indefiniteness / Section 101 Rejections.**

Initially, Claims 16 and 18 were rejected under Section 112, second paragraph as allegedly being indefinite and were also rejected under Section 101. Under Section 112, the Examiner contends that Claims 16 and 18 are indefinite in that they recite a use without any active, positive steps delimiting how this use is to be practiced. Under Section 101, the Examiner contends that the lack of steps in the claims makes Claims 16 and 18 improper process claims.

In response, the Applicants have herein cancelled Claims 16 and 18 and submitted new Claims 20 and 21 in replacement thereof. The rejections of Claims 16 and 18 are therefore moot and should be withdrawn.

II. The Enablement Rejection.

The Examiner also contends that Claim 18 lacks enablement. Claim 18 is directed to the use of the composition of claim 1 for the “treatment and/or prevention” of diseases indicated for erythropoietin (EPO). The Examiner contends that such “treatment” is enabled but that the recited “prevention” is not enabled in the specification.

As noted above, Claim 18 has been cancelled and replaced by new Claim 21. Thus, the enablement rejection is moot and should be withdrawn. It is noted that in new Claim 21, the limitation “and/or prevention” has been deleted.

III. The Written Description Rejection.

The Examiner further contends that Claim 2 fails to satisfy the written description requirement of Section 112. Specifically, the Examiner objects to the term “additives” and contends that “the specification does not provide a reasonably representative disclosure of useful ‘additives’ generally.”

In response, the Applicants have herein amended Claim 2 to delete the term “additives” and recite instead that the composition is free of serum proteins, other than EPO, derived from human and/or animal origin. In view of this amendment, it is submitted that the written description rejection has been overcome and that the same should be withdrawn.

IV. The Indefiniteness Rejections.

Claims 1 – 13, and 18 were further rejected under Section 112, second paragraph as allegedly being indefinite.

With regard to Claim 1, and by extension each of its dependent Claims 2 – 13 and 18, the Examiner contends that the recitation of the term “essentially” render the claim indefinite.

It is respectfully submitted that this grounds of rejection is improper and should be withdrawn. The term “essentially” is used on in the transition phrase “consisting essentially of.” The “consisting essentially of” is both proper and conventionally to use in patent claims. Such a claim is “partially closed” in that its

scope excludes additional elements which would materially affect the basic and novel characteristics of the claimed invention. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984); *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351 (Fed. Cir. 1998). Thus, in the present claims, the transition “consisting essentially of” partially closes the claims to exclude additional materials which materially affect the basic and novel characteristics of the claimed composition.<sup>1</sup> For instance, the claims exclude further EPO stabilizers (such as urea) beyond those recited in the claims.

With further regard to Claim 2, the Examiner also contends that the term “additives” is indefinite. As noted above, however, Claim 2 has been amended herein to delete the term “additives” and recite instead that the composition is free of serum proteins, other than EPO, derived from human and/or animal origin. In view of this amendment, it is submitted that the indefiniteness rejection of Claim 2 is and that the same should be withdrawn.

#### V. The Prior Art Rejections.

Once again, Claims 1 and 3 – 13 were rejected as allegedly being anticipated by the Woog patent, and Claim 16 was rejected as allegedly being obvious over the Woog patent taken in combination with the Cymbalista patent. The Applicants respectfully disagree.

As noted above, Claim 1, and thus each of its dependent claims as well, is a composition claim written in the partially closed “consisting essentially of” format.<sup>2</sup> Thus, in Claims 1 and 3 – 13, the transition “consisting essentially of” partially closes the claims to exclude additional materials which materially affect the basic and novel characteristics of the claimed composition. For instance, the claims exclude further EPO stabilizers (such as urea) beyond those recited in the claims.

The Woog patent fails to disclose or suggest such a composition. Instead, Woog teaches an erythropoietin (EPO) composition in which urea is present as the

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<sup>1</sup> The Applicants have also added new Claim 19 to the case in which the fully closed “consisting of” transition is used.

<sup>2</sup> It should also be noted that the Applicants have amended Claim 1 to clarify which components of the composition are mandatory and which are optional.

main EPO stabilizer. According to Woog, the use of a urea stabilizer is not optional, but mandatory. In fact, Woog goes so far as to say the addition of urea is “[d]ecisive for stabilization” of the EPO. *See*, Woog, Col. 2, lines 43 – 44.

For at least this reason, Woog cannot be said to anticipate the subject matter of Claim 1 or dependent Claims 3 – 13.

The Examiner also argues that Claim 16 is obvious over Woog taken in combination with Cymbalista. According to Claim 16, erythropoietin (EPO) is to be stabilized in an aqueous solution using only polyvinylpyrrolidone (PVP) as a stabilizer. Once again, however, Woog teaches a composition in which urea, not PVP, is the principal and “decisive” stabilization agent for EPO. Thus Woog fails to disclose PVP as the sole stabilizer for the stabilization of EPO in an aqueous solution, a point which the Examiner acknowledges on page 12 of the current Office Action.

The Examiner attempts to cure this deficiency in Woog with the Cymbalista patent, arguing that Cymbalista discloses the stabilization of “a protein with PVP.” In view of this disclosure, the Examiner contends that it would have obvious to include PVP as the sole stabilizer in Woog.

The Applicants submit that the Examiner’s proposed combination of the Woog and Cymbalista references would not have lead a person of ordinary skill to the subject matter of Claim 16. While Cymbalista may disclose the stabilization of “a protein” with PVP, the protein being stabilized in Cymbalista is interferon  $\beta$ , not erythropoietin. In fact, Cymbalista says nothing at all about erythropoietin, stabilized or otherwise. Those of ordinary skill in the art recognize that all proteins are not interchangeable since the structures of different proteins vary widely. Likewise, those of skill recognize that a stabilizer which is effective for one protein may be inappropriate and ineffective for stabilizing a different protein.

Thus, the fact that Cymbalista discloses the stabilization of interferon  $\beta$  with PVP would not have lead one of ordinary skill in the art to conclude that PVP could, by itself, stabilize EPO, particularly when Woog unequivocally states that urea is decisive and necessary for the stabilization of EPO. Instead, one of ordinary skill would have disregarded Cymbalista’s teachings as being limited to the stabilization of interferon  $\beta$ , rather than the stabilization of EPO.

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For at least this reason, it is submitted that the obviousness rejection of Claim 16 based upon the combination of Woog and Cymbalista is improper and should be withdrawn .

VI. The Provisional Double Patenting Rejections.

Finally, Claims 1 – 13, 16, and 18 were provisionally rejected for alleged obviousness-type double patenting based upon Claims 1 – 20 of copending application 10/521,298. Such rejections are of course obviated by the filing of an appropriate terminal disclaimer. A terminal disclaimer is submitted herewith for this purpose disclaiming that portion of the patent term of the patent to issue from this application which would extend beyond the term of any commonly owned patent which may issue from the '298 application. Accordingly, the double patenting rejection is overcome and the same should be withdrawn.

In light of the foregoing, the Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355.**

Respectfully submitted,  
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